REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of the Claims

Claims 1, 26, 43 and 57 are currently being amended. Claims 62-70 are being added. No new matter is added.

Claim rejections under 102(b) and 103

Claims 1-4, 7-10, 12-16, 26-30, 33-36, 38, 43-46, 49 and 57-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulman et al. (U.S. Patent No. 5,497,772). Claims 5-6, 11, 31-32 and 47-48 are rejected under 35 U.S.C. 103(a) as being obvious over Schulman et al. in view of Riedel (U.S. Patent No. 6,069,011). These rejections are respectfully traversed.

Claim 1 and 43, as amended, recite among other features, a method for verifying the integrity of sensor data comprising:

> receiving a first data value from the sensor having a first parameter that exceeds a first threshold value;
> determining that the first parameter relating to the first data value exceeds the first threshold value;
> continuing receipt of data from the sensor after determining that the first parameter relating to the first data value exceeds the first threshold value;
> receiving a second data value from the sensor, after determining the first parameter relating to the first data value exceeds the first threshold value, the second data value having a first parameter that exceeds the first threshold value;
> determining that the first parameter relating to the second data value exceeds the first threshold value after determining a first parameter relating to the first data value exceeds the first threshold;
> terminating receipt of data from the sensor in response to determining that the first parameters relating to the first and the second data values exceed the first threshold value. (*emphasis added*)

Schulman et al. and Reidel fail to teach or suggest at least the above recited features of claims 1 and 43. The Office Action of July 02, 2009 cites Schulman et al. as disclosing at least some of the above recited features of claims 1 and 43. The Office Action of July 02, 2009 cites

to block 282 of figure 11 and settable limits disclosed on column 3, lines 57-59, as reciting the terminating receipt feature. However, Schulman et al. fails to teach or suggest, terminating receipt of data from the sensor in response to determining that the first parameters relating to the first and the second data values exceed the first threshold value. Instead, Schulman et al. teaches a continuous glucose sensor that samples every minute and displays the new glucose data. (Schulman, column 15, lines 50-60; Fig. 11, block 274) Moreover, Schulman discloses:

> It is an additional feature of the invention to provide such a glucose monitoring system that has settable limits above or below which the measured glucose concentration, or the rate of change (trend) of the glucose concentration, may not go without flashing and/or sounding an alarm. (*emphasis added*, Schulman, column 3, lines 57-62)
>
> . . .
>
> The glucose data, including the computed rate of change is compared to the limits associated with the alarms (block 278). If any of the alarm limits have been exceeded, then an alarm message is flashed on the screen (block 280), and the monitor beeps (block 282). The beeping can be silenced by touching a silence button on the screen, but the flashing alarm message continues until such time as the condition which triggered the alarm is corrected as evidence by new sensor data. (*emphasis added*, Schulman, column 15, lines 65 to column 16 line 6)

The above portions of Schulman et al. teach, settable limits that may trigger a flashing alarm or beep and the flashing alarm message continues until such time as the condition which triggered the alarm is corrected. In order to determine, that the condition which triggered the alarm (exceeding the settable limits) is corrected, Schulman et al. continues to receive new data and evaluate it against the settable limits. Thus, Schulman et al. fail to teach or suggest, terminating receipt of data from the sensor in response to determining that the first parameters relating to the first and the second data values exceed the first threshold value.

Schulman et al. may to stop performing the above loop by determining that it is time to recalibrate (block 284) (Schulman et al., column 16, lines 23-30 and Fig. 11). However, Schulman et al. teaches that recalibration may be performed every 24 hours, and must be performed within 26 hours of the last calibration. (Schulman et al, column 16, lines 23-30) Thus the recalibration is not performed in response to determining that the first parameters relating to the first and the second data values exceed the first threshold value.

Moreover, Schulman et al. fail to realize advantages that my be realized by the aspect of the claimed invention. Aspects of the claimed invention relate to terminating receipt of data or discarding sensor data upon a possible failed sensor situation. Instead, Schulman et al. is directed to detecting a glucose value that exceeds a settable limits in response to exceeding the limits. Schulman et al alerts the patient by a visual or audible alarm and continues to alert the patient. Therefore, Schulman et al. fails to realize the advantages of the aspects of the claimed invention of claims 1 and 43.

Therefore Schulman et al. fails to teach or suggest at least the above recited features of claims 1 and 43.

Riedel fails to teach or suggest, terminating receipt of data from the sensor in response to determining that the first parameters relating to the first and the second data values exceed the first threshold value. Instead, Riedel is directed to determining the start of the incubation time period for a reagent matrix that is exposed to sample fluid using the maximum first and/or second derivative values. (Riedel, column 6, lines 21-24) Thus Schulman et al. and Reidel, alone or in combination, fail to teach of suggest at least the above recited features of claims 1 and 26.

Therefore claims 1 and 43 are believed to be allowable. Because claims 2-16 and 44-49 depend from claims 1 and 43 respectively, they are believed to be allowable for at least the same reasons claims 1 and 43 are believed to be allowable.

Claims 26 and 57 are amended to recite, a method for calibrating a sensor by:

> receiving a plurality of data values from the sensor;
> determining the reliability of each data value of the plurality of data values;
> discarding data values after receiving at least two data values that are unreliable;
> filtering the data values of the plurality of data that have not been discarded; and
> adjusting an output of the sensor using the filtered data values.

Schulman et al. and Reidel, alone or in combination fail to teach or suggest at least the above recited features of claims 26 and 57. The Office Action of July 2, 2009 cites Schulman et al. as disclosing some of the above recited feature of claims 26 and 57. In particular the Office

Action cites to block 302 withdraw blood sample, normalize 296, block 310 adjust normalization constant (figure 12). None of the above steps from Schulman et al., withdraw blood sample, normalize or adjust normalization constant, teach or suggest, discarding data values after receiving at least two data values that are unreliable. Reliability of the data values is not mentioned in the calibration process shown in figure 12. Normalization does not refer to discarding data values after receiving at least two data values.

Riedel fails to teach or suggest, terminating receipt of data from the sensor discarding data values after receiving at least two data values that are unreliable. Instead, Riedel is directed to determining the start of the incubation time period for a reagent matrix that is exposed to sample fluid using the maximum first and/or second derivative values. (Riedel, column 6, lines 21-24) Thus Schulman et al. and Reidel, alone or in combination, fail to teach of suggest at least the above recited features of claims 1 and 26.

Therefore claims 26 and 57 are believed to be allowable. Because claims 27-42 and 58-61 depend from claims 26 and 57 respectively, they are believed to be allowable for at least the same reasons claims 26 and 57 are believed to be allowable.

New Claims

New claims 62 – 69 are added to further protect aspects of the present invention. New claims 62 – 69 are supported by the present disclosure, for example, at least with respect to claims 62 and 66 (Figs. 19-20, Paragraphs [0148] and [0148]), claims 63-65 and 67-69 (Figs. 2 and Paragraph [0037]). New claims 62-65 are each dependent on independent claim 1. Accordingly, each of the new claims 62-65 are patentably distinguishable over the references of record, at least for reasons as discussed above with respect to claim 1. New claims 66-69 are each dependent on independent claim 43. Accordingly, each of the new claims 66-69 are patentably distinguishable over the references of record, at least for reasons as discussed above with respect to claim 43. In addition each new claim 62-69 are further distinguished from the references of record.

For example, new claims 62 and 66 are dependent on claims 1 and 43, respectively, and incorporate every feature of the parent claim and further recites, displaying the data values to a patient after the first parameter of the first data value exceeds the first threshold value. Instead,

Schulman et al. teach displaying an alert or a audible alarm upon determining that the data value is outside the set limits. Reidel fails to teach or suggest the above recited features. Therefore, claim 62 and 66 are believed to be allowable.

For example, new claim 63 is dependent on claims 1 and 62, and new claim 67 is dependent on claims 43 and 66, and they each incorporate every feature of the parent claims and further recite, terminating receipt of data from the sensor further terminating displaying the data values to the patient after, both, the first parameter of the first data value exceeds the first threshold value and the first parameter of the second data value exceeds the first threshold value. As discussed above regarding claim 1, Schulman et al. and Reidel, fail to teach or suggest terminating receipt of data from the sensor further terminating displaying the data values to the patient after, both, the first parameter of the first data value exceeds the first threshold value and the first parameter of the second data value exceeds the first threshold value. Therefore, claims 63 and 67 are believed to be allowable.

For example, new claim 64 and 68 are dependent on claims 1 and 43, and incorporate every feature of the parent claims and further recite, terminating processing the data values to determine a glucose value from the data values. As discussed above regarding claim 1, Schulman et al. and Reidel fail to teach or suggest, terminating processing the data values to determine a glucose value from the data values. Therefore, claims 64 and 68 are believed to be allowable.

For example, new claims 65 and 69 are dependent on claims 1 and 43, respectively, and incorporate every feature of the parent claims and further recite, terminating receipt of the data occurs when both the first parameter of the first data value and the first parameter of the second data value exceed the first threshold value within 1 hour. Schulman et al. and Reidel fail to teach or suggest, terminating receipt of the data when both the first parameter of the first data value and the first parameter of the second data value exceed the first threshold value within 1 hour. Therefore, claims 65 and 69 are believed to be allowable.

Concluding Remarks

After amending the claims as set forth above, claims 1-16, 26-49, 57-69 are pending in this application. Applicant believes that the present application is now in condition for

allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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